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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/561,700 | 11/10/2006 | Isa Odidi | 221904-1050 | 8166 |
| 24504 7590 04/17/2009 THOMAS, KAYDEN, HORSTEMEYER & RISLEY, LLP 600 GALLERIA PARKWAY, S.E. STE 1500 ATLANTA, GA 30339-5994 | | | | |
| EXAMINER | | | | |
| PURDY, KYLE A | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1611 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 04/17/2009 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/561,700

Applicant(s)

ODIDI ET AL.

Examiner

Kyle Purdy

Art Unit

1611

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 30 March 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3+1 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1-28 and 31-45.
Claim(s) withdrawn from consideration: 29, 30 and 46-48.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

/Kyle Purdy/
Examiner, Art Unit 1611

/David J Blanchard/
Primary Examiner, Art Unit 1643

Continuation of 11, does NOT place the application in condition for allowance because: the amendments do not overcome the rejections of record.

Applicants arguments filed 03/30/2009 regarding the rejection of claims 1-28 and 31-45 made by the Examiner under 35 USC 103(a) over Phillips (US 2002/0045646) in view of Bergstrand et al. (US 5817338) have been fully considered but they are not persuasive. The rejection of claims 1-28 and 31-45 made by the examiner under 35 USC 103(a) is MAINTAINED for the reasons of record in the office action mailed on 01/29/2009.

In regards to the 103(a) rejection, Applicant asserts the following:

A) None of the references teaches each of the populations as being selected from a population of beads, pellets, tablets, granules and combinations thereof; and

B) Bergstrand teaches away from using a capsule.

In response to A, the Examiner disagrees. Phillips teaches that the multifunctional tablet comprising discrete delivery system comprising compressed granules of omeprazole and free sodium bicarbonate as well as enterically coated omeprazole granules. Bergstrand teaches the use of enterically coated granules comprising a separating layer in their pharmaceutical preparations. Thus, as each of the reference employs granules for their formulations, any person of ordinary skill in the art would endeavor to, at the very least, use granules as presently claimed. Applicants argument is not found persuasive.

With respect to assertion B, Bergstrand is not relied upon for its teaching a capsule structure. The primary reference to Phillips suggests that limitation. Bergstrand is relied upon for their teaching of a separating layer between the PPI core and the enteric coating layer. As was noted in the office action mailed on 03/18/2008, Bergstrand teaches that PPI compounds are acid labile and the enteric coatings are generally acidic. If the PPI core were coated directly with an enteric coating, the PPI would slowly degrade thereby eliminating some of the PPIs pharmaceutical efficacy. Bergstrand teaches that by putting an alkaline separating layer between the core and the enteric coating layer results in a more chemically stable structure suitable for long term storage. One would have been motivated to include in the capsule formulation taught by Phillips such an enterically coated PPI granule comprising a separating layer between the enteric coating and the core. Applicants argument is not found persuasive.